

EXHIBIT 4

COMMONWEALTH OF MASSACHUSETTS

EASTERN COUNTIES, ss.

SUPERIOR COURT

-----x
IN RE MASSACHUSETTS STATE :
COURT DIET DRUG LITIGATION :
-----x

Civil Action
No. 00-9999-G

-----x
KARLA SAWYER, LINDA PAUL,
JEANNIE ROSE and JOYCE PALOMBA,
-----x

Plaintiffs, :
-----x
Civil Action No. 03-5028-B
(Middlesex County)

v.
-----x

INDEVUS PHARMACEUTICALS, INC.,
f/k/a INTERNEURON
PHARMACEUTICALS, INC.,
-----x

Defendant. :
-----x

**INDEVUS' MEMORANDUM OF LAW IN
SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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Defendant, Indevus Pharmaceuticals, Inc. ("Indevus"), by its attorneys, submits this Memorandum of Law in Support of Motion for Summary Judgment:

INTRODUCTION

This action concerns the drug Redux (dexfenfluramine), a prescription drug used in the management of obesity, which was withdrawn from the market over six years before this lawsuit was filed on December 11, 2003. In 1990, Indevus (then known as Interneuron Pharmaceuticals, Inc.) licensed the rights to manufacture and sell dexfenfluramine in the United States from Les Laboratoires Servier, a French company. Dexfenfluramine was the right-sided isomer of fenfluramine, which was already in distribution in the United States by American Home Products Corporation (now known as Wyeth) under the brand name Pondimin. Indevus sublicensed the rights to dexfenfluramine to a Wyeth predecessor and entered into a co-promotion agreement with Wyeth regarding the marketing, distribution and post-market surveillance of dexfenfluramine in the United States. Indevus was the sponsor of Redux's application for approval by the U.S. Food and Drug Administration ("FDA"). Redux was first sold in the United States in 1996, following FDA approval.¹

In July, 1997, doctors at the Mayo Clinic reported a possible association between the use of diet drugs and valvular heart disease. The Mayo Clinic observation, which was widely covered in national and local broadcast and print media, was the subject of scientific and government attention. On September 15, 1997, Pondimin and Redux were both withdrawn from the market by Wyeth and Indevus. The withdrawal of the two drugs was front page news throughout the country and a lead story on most national and local television newscasts.

Virtually within days after the drugs were withdrawn from the market, hundreds of lawsuits were filed against Wyeth and Indevus. On December 10, 1997, the Judicial Panel on Multidistrict Litigation created a multidistrict litigation docket presided over by Judge Bechtle of

¹ See generally *In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2001 WL 497313, at *1 & nn.2-3 (E.D. Pa. May 9, 2001).

the United States District Court for the Eastern District of Pennsylvania.² In or about April 1999, counsel for various state and federal plaintiffs and Wyeth began negotiating a nationwide class action settlement. The principal terms of the settlement were captured in a Memorandum of Understanding in October 1999 and conditionally approved by the MDL court on November 23, 1999. The settlement was approved by the MDL court on August 28, 2000.³ Indevus was not a party to the nationwide class action settlement.

The nationwide settlement with Wyeth contained certain provisions that permitted class members to exercise so-called "intermediate" and "back-end opt-out" rights under certain conditions. *Wyeth* agreed not to assert a statute of limitations defense provided such claims were brought within a specified period after proper assertion of an intermediate or back-end opt-out.⁴ Again, Indevus was not a party to the nationwide settlement and is not bound by Wyeth's agreement to waive any statute of limitations defense. As to Indevus, it is clear that Plaintiffs' actions cannot stand.

SUMMARY OF ARGUMENT

These stale claims were long ago barred by the applicable three-year and four-year statutes of limitations. They are not saved by the discovery rule because valvular heart disease associated with diet drug use is not a latent injury. Judge Bechtle so found in approving the nationwide class action settlement and, as class members, Plaintiffs are collaterally and judicially estopped from challenging his findings. Furthermore, the market withdrawal of Redux and Pondimin in September 1997 was the subject of intense publicity at both the national and local levels. And the publicity concerning the possible association between heart disease and the drugs continued while the limitations period ran. As a result, Plaintiffs were on notice of their

² See *id.*

³ See *Brown v. Am. Home Prods. Corp. (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)*, Nos. 1203, 99-20593, 2000 WL 1222042, at *4-5, *69 (E.D. Pa. Aug. 28, 2000).

⁴ See *id.* at *21.

claims and could have discovered any alleged injuries in September, 1997. Their claims against Indevus are, therefore, barred.

Likewise, the statute of limitations was not tolled. Plaintiffs have not alleged any facts to support a claim of tolling by fraudulent concealment. Nor are Plaintiffs' claims tolled by the pendency of certain class actions. Initially, the Massachusetts Supreme Judicial Court has never recognized class action tolling and would not do so in a case such as this, involving mass tort, personal injury lawsuits. Further, even if Massachusetts did adopt a class action tolling rule, it would not save Plaintiffs' claims. Application of such a rule in this case would be barred or limited by various impediments. Significantly, the United States Supreme Court and other courts have held that in order to take advantage of a class action toll, a plaintiff must file within the extension period provided by the most analogous state savings statute, in this case one year. Because this lawsuit was not filed within one year following dismissal of the last possibly relevant class action, Plaintiffs' claims are barred.

When a defendant pleads the statute of limitations as a defense and establishes that the lawsuit was filed more than three years (or four years in the case of G.L. c. 93A actions) after the injury occurred, the burden of proving facts to establish that the case is not barred by limitations shifts to the plaintiff. *Franklin v. Albert*, 381 Mass. 611, 619, 411 N.E.2d 458, 463 (1980). For the reasons discussed below, Plaintiffs have not pleaded, and cannot establish, facts sufficient to save their claims from a limitations bar. Massachusetts courts have shown no hesitancy in granting summary judgment on limitations grounds when plaintiffs have failed to act with reasonable diligence to discover their causes of action. See, e.g., *Albrecht v. Clifford*, 436 Mass. 706, 715-16, 767 N.E.2d 42, 49-50 (2002); *Bowen v. Eli Lilly & Co.*, 408 Mass. 204, 204-05, 557 N.E.2d 739, 740 (1990). As a result, Plaintiffs' claims must be dismissed.

ARGUMENT

I. Plaintiffs' Causes of Action Accrued No Later Than the Fall of 1997

A. The Statute of Limitations Began To Run When Plaintiffs Should Have Known of Their Injuries

Plaintiffs' claims for strict products liability (Counts I and II),⁵ negligence (Count III), and fraudulent misrepresentation (Count IV) are each governed by a three-year limitations period under Massachusetts law. *See M.G.L.A. c. 260, § 2A; M.G.L.A. c. 106, § 2-318; see also Martinez v. Sherwin Williams Co.*, 50 Mass. App. Ct. 908, 908, 737 N.E.2d 927, 928 (2000); *McEneaney v. Chestnut Hill Realty Corp.*, 38 Mass. App. Ct. 573, 577, 650 N.E.2d 93, 96 (1995). Plaintiffs' claim for alleged violations of Massachusetts' Consumer Protection Act (Count V) is governed by a four-year statute of limitations. *See M.G.L.A. c. 260, § 5A.*⁶

As a general rule, a statute of limitations begins to run from the "time of injury." *See Cannon v. Sears, Roebuck & Co.*, 374 Mass. 739, 742, 374 N.E.2d 582, 584 (1978); M.G.L.A. c. 106, § 2-318. However, with respect to alleged "inherently unknowable" wrongs,⁷ Massachusetts applies the discovery rule, which provides that a plaintiff's cause of action does not accrue until she learns, *or reasonably should have learned*, that she has been harmed by the defendant's conduct. *See Olsen v. Bell Telephone Labs., Inc.*, 388 Mass. 171, 174-75, 445

⁵ Although Plaintiffs describe the first and second counts as "strict products liability," Massachusetts does not recognize claims for strict liability in tort for defective products. *See Commonwealth v. Johnson Insulation*, 425 Mass. 650, 653, 682 N.E.2d 1323, 1326 (1997). Rather, Massachusetts' liberal version of the implied warranty of merchantability establishes liability "as comprehensive as that to be found in other jurisdictions that have adopted the tort of strict product liability." *Id.*

⁶ Massachusetts will apply its own statute of limitations to cases brought in its jurisdiction unless (1) maintenance of the claim would serve no substantial interest of the forum *and* (2) the claim would be barred under the law of the state with a more significant relationship to the parties and the occurrence. *See New England Tel. & Tel. Co. v. Gourdeau Constr. Co.*, 419 Mass. 658, 660, 647 N.E.2d 42, 43 (1995) (adopting section 142 of the Restatement (Second) of Conflict of Laws). If the action would be barred under Massachusetts' statute of limitations, as is the case here, then the Court need not engage in a choice of law analysis.

⁷ A wrong is "inherently unknowable" when the plaintiff does not know, or could not through the exercise of reasonable diligence have known, the facts underlying his cause of action. *See Albrecht v. Clifford*, 436 Mass. 706, 714-15, 767 N.E.2d 42, 49 (Mass. 2002).

N.E.2d 609, 61 1-12 (1983); *Fidler v. E.M. Parker Co.*, 394 Mass. 534, 544-45, 476 N.E.2d 595, 601-02 (1985). The discovery rule in Massachusetts is narrow and does not require notice of every element (duty, breach, causation and damages) before the limitations period starts to run. See *Krasnow v. Allen*, 29 Mass. App. Ct. 562, 568-69, 562 N.E.2d 1375, 1379 (1990).

Inquiry notice, not actual notice, is all that is required for the statute of limitations to start running. "[T]he statute of limitations starts to run when an event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury." *Bowen*, 408 Mass. at 207, 577 N.E.2d at 741.

"The [discovery rule] does not require that the plaintiff know or have reason to know that the defendant violated a legal duty to the plaintiff, but only that she knew *or had reason to know* that she had been harmed by the defendant's conduct." "Thus, on notice, the potential litigant has the duty to discover from the legal, scientific, and medical communities whether the theory of causation is supportable and whether it supports a legal claim."

Sheila S. v. Commonwealth, 57 Mass. App. Ct. 423, 428, 783 N.E.2d 868, 874 (2003) (emphasis added; alteration in original; citations omitted). The relevant inquiry is when a "reasonable person in [the plaintiff's] position would have possessed knowledge or sufficient notice that they were harmed and what the cause of the harm was." *Phinney v. Morgan*, 39 Mass. App. Ct. 202, 208, 654 N.E.2d 77, 81 (1995). Thus, a plaintiff's alleged ignorance of his injury is insufficient to prevent the statute of limitations from running when reasonable investigation would have caused him to discover his injury. See *Albrecht*, 436 Mass. at 715-16, 767 N.E.2d at 49-50; *Myers v. Agoritsas*, No. 930844, 1994 WL 879696, at *3 (Mass. Super. Ct. May 4, 1994).

For example, in *Olsen*, the plaintiff argued that his action did not accrue until he learned that his injury was permanent. The Massachusetts Supreme Judicial Court rejected such argument, observing:

Statutes of limitations are "vital to the welfare of society. . . . They promote repose by giving security and stability to human affairs." They also "encourage plaintiffs to bring actions within prescribed deadlines when evidence is fresh and available." Adoption of [the plaintiff's] argument that a claim for permanent injury accrues only when the permanency is, or should have been discovered, would create an unacceptable imbalance between affording plaintiffs a remedy and providing defendants the repose that is essential to stability in human affairs.

388 Mass. at 175, 445 N.E.2d at 612 (omission in original; citations omitted).

Accordingly, failure to timely seek medical confirmation will not delay accrual of a plaintiff's claim. In *Martinez*, the plaintiff began experiencing symptoms of the injury for which she sued in 1985 and suspected that her symptoms were caused by her work environment. She did not, however, see specialists to confirm the cause of her symptoms until 1990. The court rejected the plaintiff's argument, holding that the plaintiff's failure to consult with medical experts for more than six years after her symptoms appeared doomed her complaint. *Martinez*, 50 Mass. App. Ct. at 908-09, 737 N.E.2d at 928-29.

Likewise, in *Lareau v. Page*, 840 F. Supp. 920 (D. Mass. 1993), *aff'd*, 39 F.3d 384 (1st Cir. 1994), the court held that the plaintiff was on inquiry notice when she received a letter from her physician indicating that "there was 'a theoretical possibility'" that a radioactive contrast dye "could 'induce a tumor in surrounding brain tissue.'" 840 F. Supp. at 923, 926-27. As the court explained, the plaintiff's "reluctance to credit" her doctor's warning (even though she had received a contrary second opinion) did not toll the statute. *Id.* at 926. A plaintiff's action accrues notwithstanding division among the medical community. *Id.* Similarly, in *Kay v. Johnson & Johnson*, 722 F. Supp. 874 (D. Mass. 1989), *aff'd*, 902 F.2d 1 (1st Cir. 1990), the court observed that the plaintiff's awareness of her symptoms and suspicion that her condition was caused by oral contraceptives was "sufficient to trigger the running of the limitation period," notwithstanding conflicting medical advice received by the plaintiff. 722 F. Supp. at 881.

B. There Is No Latency Period for Valvular Heart Disease Attributable to Use of Redux

In this case, Plaintiffs' injuries were not "inherently unknowable." First, valvulopathy associated with Redux use is not a latent disease. This unassailable fact has been documented by numerous studies, a collection of which is attached to the Declaration of Katherine Armstrong as Exhibit 6.

This issue was also specifically considered by Judge Bechtle in the MDL. Having presided over the MDL for two and a half years and after considering a wealth of scientific

evidence, including expert testimony, submitted in connection with the Wyeth class action settlement, he concluded: "[T]hese [valvular] lesions [attributable to Pondimin and Redux] are not latent. If they are going to occur, they are going to occur during drug use (or shortly thereafter) and be demonstrable on echocardiogram." *Brown v. Am. Home Prods. Corp. (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)*, Nos. 1203, 99-20593, 2000 WL 1222042, at *18 (E.D. Pa. Aug. 28, 2000). As Judge Bechtle explained:

The clinical and epidemiological studies demonstrate – and all the experts agree – that insofar as the use of fenfluramine or dexfenfluramine results in an increased prevalence of valvular regurgitation, that regurgitation is detectable by echocardiogram shortly after the patients discontinue use of diet drugs. Conversely, there is no evidence that the use of the drugs results in any increased risk of regurgitation that is "latent" and not detectable by today's sophisticated echocardiographic technology.

The absence of a latency period between ingestion of fenfluramine and/or dexfenfluramine and the development of clinically detectable VHD [valvular heart disease] is also confirmed by a number of studies that have followed former fenfluramine/dexfenfluramine patients for a number of years, either through the use of echocardiograms or comprehensive medical record review. Each of these studies finds that there was no emergence of new disease after some latency period.

Id. at *46 (citations and footnote omitted).

Redux was removed from the market in September 1997. The latest date that any of these Plaintiffs alleges she took the drug was September 15, 1997, the date of its withdrawal. (Paul Product Identification Due Diligence Statement, Armstrong Decl., Ex. 2.) Plaintiff Sawyer alleges that she last used the drug in August, 1997; Rose in August, 1997 and Palomba in December, 1996. (Sawyer Interrogatory Responses, Rose and Palomba Product Identification Due Diligence Statements, Armstrong Decl., Exs. 1, 3 & 4.) Plaintiffs' alleged injuries (assuming that they are injured and that such injuries are attributable to Redux) would have been detectable on echocardiogram shortly after they discontinued use of the drug.⁸

⁸ The determination that valvular heart disease attributed to Redux is not latent is also relevant to the issue of causation. That is, if there was no disease detectable on echocardiogram shortly after cessation of Redux use, valvular insufficiency that occurred years after Redux use could not have been caused by Redux. For example, Plaintiff Sawyer had an echocardiogram performed in October, 1997. The conclusion of the report was "[t]rivial mitral prolapse with insignificant mitral regurgitation." (Armstrong Decl., Ex. 5.) If Plaintiff Sawyer attributes this condition to her Redux use, the finding clearly triggered the limitations period. See *Olsen*, 388 Mass. at 175, 445 N.E.2d at 612. If she contends that the report supports the absence of disease, then it negates causation as to any later finding of valvular insufficiency.

**1. Plaintiffs Are Collaterally Estopped from
Arguing That Their Alleged Injuries Were Latent**

In any event, Plaintiffs are barred from relitigating the issue of latency by the doctrines of collateral and judicial estoppel. Collateral estoppel bars a party from relitigating issues decided in a prior litigation if

- (1) the issue decided in the prior case is identical to one presented in the later case;
- (2) there was a final judgment on the merits; (3) the party against whom the plea is asserted was a party or in privity with a party in the prior case; (4) the party or person privy to the party against whom the doctrine is asserted had a full and fair opportunity to litigate the issue in the prior proceeding and (5) the determination in the prior proceeding was essential to the judgment.

City of Pittsburgh v. Zoning Bd. of Adjustment, 559 A.2d 896, 901 (Pa. 1989). The U.S. Supreme Court has made clear that "whether a Federal judgment has been given due force and effect in the state court is a Federal question" governed by federal law. *Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 507 (2001) (citation omitted). As a matter of federal law, courts should look to the law of the state where the federal court sits to determine the preclusive effect of its judgments. *See id.* at 508. Accordingly, Pennsylvania law governs the collateral estoppel issue in this case.⁹

Collateral estoppel plainly applies here. Plaintiffs were members of a National Diet Drug Settlement Class approved by the MDL court in *Brown*.¹⁰ "A judgment in a properly entertained class action is binding on all class members in any subsequent litigation. Class members who elect not to opt out of a class action are 'full members who must abide by the final judgment

⁹ Notably, there is no actual conflict for this Court to decide because the elements for collateral estoppel are essentially the same under Pennsylvania, federal and Massachusetts law. *See Migra v. Warren City Sch. Dist. Bd. of Educ.*, 465 U.S. 75, 77 n.1 (1984); *Miles v. Aetna Cas. & Sur. Co.*, 412 Mass. 424, 426-27, 589 N.E.2d 314, 316-17 (1992).

¹⁰ The *Brown* class included "all persons in the United States who ingested Pondimin and Redux and their associated consortium claimants." *Brown*, 2000 WL 1222042, at *19. Plaintiffs may characterize themselves as "intermediate opt-outs," referring to a provision of the *Brown* settlement which allowed class members to pursue claims against Wyeth subject to certain conditions. *See id.* at *21. In other words, such persons could opt-out of the settlement, *but not out of the class*. They continue to be members of the class and bound by the judgment in *Brown*. *See Alexander v. Wyeth (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)*, MDL No. 1203, Civil Action Nos. 03-20206, et al., slip op. at 2-3 (E.D. Pa. Jan. 29, 2004). For example, under the terms of the *Brown* settlement agreement, such class members cannot pursue claims for punitive damages, multiple damages, consumer fraud or medical monitoring against Wyeth. *See Brown*, 2000 WL 1222042, at *25.

whether favorable or adverse.'" *Taylor v. Shiley, Inc.*, 714 A.2d 1064, 1066 (Pa. Super. Ct. 1998) (citations omitted); *accord Sica v. City of Phila.*, 30 Pa. D. & C. 3d 371, 384 (Pa. Ct. Com. Pl. 1982).¹¹ Indeed, to conclude otherwise would run contrary to the essential nature and purpose of class actions.

The fact that Indevus was not a party to *Brown* is of no moment. "Mutuality of the parties, once the rule, has now been abolished in Pennsylvania. The only requirement is, logically, that the party *against whom estoppel is asserted* be a party to the prior adjudication." *Witkowski v. Welch*, 173 F.3d 192, 200 n.10 (3d Cir. 1999) (citing *In re Estate of Ellis*, 333 A.2d 728, 730-31 (Pa. 1975)).¹²

The issue of latency was fully litigated in *Brown* and the MDL court's determination of this issue was essential to its judgment. Prior to the fairness hearing, the MDL court allowed extensive discovery regarding the class action settlement. See *Brown*, 2000 WL 1222042, at *5-6. The fairness hearing lasted several days, during which extensive testimonial and documentary proof was submitted. "[T]he proponents of the Settlement Agreement and the persons who objected to the settlement . . . had a full and fair opportunity to offer all of the evidence that they wished to tender to the court concerning" the settlement. *Id.* at *6. Objectors to the settlement submitted studies to the court in support of their latency arguments; however, the court determined that such studies did not, in fact, find evidence of latency. See *id.* at *56-57. The court weighed such evidence against the substantial evidence submitted by the proponents of the settlement and concluded that there was no latency. See *id.* at *46-47.

¹¹ See also *Golden v. Pac. Maritime Ass'n*, 786 F.2d 1425, 1427, 1429 (9th Cir. 1986) (holding that class member's suit against class counsel was barred by court's implicit finding of adequacy of representation); *Laskey v. UAW*, 638 F.2d 954, 957 (6th Cir. 1981) (same; noting that adequacy of representation was "essential to approving the [class] settlement"); *Thomas v. Albright*, 77 F. Supp. 2d 114, 121-22 (D.D.C. 1999), aff'd, 247 F.3d 260 (D.C. Cir. 2001).

¹² Again, there is no actual conflict of law issue for the Court to resolve. Mutuality is also not required under Massachusetts or federal law. See *Miles*, 412 Mass. at 426-27, 589 N.E.2d at 316-17; *Monarch Life Ins. Co. v. Ropes & Gray*, 65 F.3d 973, 978 n.8 (1st Cir. 1995).

The court's determination that the effects of Redux were not latent was absolutely essential to its judgment. Under *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), it was necessary for the court to conclude that there was no disabling conflict of interest between persons presently injured and those who might be injured in the future as a result of latent effects from exposure to the drug. See *Brown*, 2000 WL 1222042, at *45-46. The court approved the settlement only after it concluded that there was no "futures" problem. See *id.* at *46. Thus, Judge Bechtle's successor as the MDL judge, Judge Harvey Bartle, has held that the Judge Bechtle's latency finding should be accorded preclusive effect.

Judge Bechtle's determination of no latency, that is that class members' injuries occurred within a short time after ingesting fen-phen, was an essential finding, for it directly affected the adequacy of class representation. Finally, PTO No. 1415, in which Judge Bechtle approved the [*Brown*] Settlement Agreement, is a final and valid judgement Thus, plaintiffs are collaterally estopped from relitigating the issue of latency

Alexander v. Wyeth (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.), MDL No. 1203, Civil Action Nos. 03-20206, et al., slip op. at 14-15 (E.D. Pa. Jan. 29, 2004) (emphasis added; citation omitted).

2. Plaintiffs Are Judicially Estopped from Arguing That Their Alleged Injuries Were Latent

Plaintiffs are also barred from relitigating the latency issue by the doctrine of judicial estoppel, which prohibits a party who successfully convinced a court to adopt a position in one case from taking a contrary position in another case. See *E. Cambridge Sav. Bank v. Wheeler*, 422 Mass. 621, 621, 664 N.E.2d 446, 446-47 (1996); *Fay v. Fed. Nat'l Mortgage Ass'n*, 419 Mass. 782, 788, 647 N.E.2d 422, 426 (1995).¹³ Plaintiffs, through their class action counsel in the *Brown* settlement proceeding, took the position that diet drug injuries were not latent; that is, that they were detectable no later than the time when use of the diet drugs ended. (See, e.g., Declaration of Dean G. Karalis, M.D. ¶ 42 (cardiology expert proffered by *Brown* class counsel) ("There is no reason to believe that there is a potential 'latent period' of any significance between

¹³ The party asserting judicial estoppel need not have been a party to the first action. See *E. Cambridge*, 422 Mass. at 623, 664 N.E.2d at 448.

the termination of diet drug exposure and the onset of valvular regurgitation. There is nothing in the experience with carcinoid disease, use of ergotamines and methyaserides or in the published literature which suggests the possibility of such latency") (Armstrong Decl., Ex. 7.) Indeed, Judge Bechtle noted in his fairness opinion that all experts presented by class counsel at the fairness hearing testified that diet drug injuries are not latent. *Brown*, 2000 WL 1222042, at *6-7 (listing plaintiffs' experts including expert on cardiology and valvular disease), *id.* at *46 (noting that all of the testifying experts agreed on the absence of latency). Accordingly, the class, which included the instant Plaintiffs, successfully convinced the court to find in their favor on the issue of latency. Had they failed to do so, the settlement would not have been approved.¹⁴

C. Plaintiffs Should Have Discovered Their Claims No Later Than the Fall of 1997

As discussed above, if Plaintiffs were injured as a result of Redux use, those injuries must have existed, if at all, at the time they stopped using Redux – no later than September 15, 1997. The association between use of Redux or Pondimin and valvular heart disease was the subject of massive publicity in the summer and fall of 1997. The Declaration of Sharon Taylor sets forth in detail the national and local publicity about diet drugs. There can be little doubt that the association between valvular heart disease and the use of diet drugs, together with the withdrawal of Redux and Pondimin on September 15, 1997, was one of the most widely covered stories in 1997. The publicity blitz began on July 8, 1997, when the Mayo Clinic issued a press release describing the health risks possibly associated with the use of diet drugs. The United States Department of Health and Human Services issued a similar press release the same day. (Taylor Decl. ¶ 5.) The Mayo Clinic report was extensively covered in both the national and regional press. (*Id.* ¶¶ 6-17.) For example, the *New York Times* and *USA Today* both ran

¹⁴ Ordinarily, judicial estoppel does not apply to settled actions. See *E. Cambridge*, 422 Mass. at 623, 664 N.E.2d at 448. A class action settlement, however, differs in important respects from an ordinary settlement. It is approved only after an adversarial hearing and results in a judgment that is binding on objectors to the settlement. Accordingly, the rationale underlying the doctrine of judicial estoppel applies with equal force to positions taken in class settlement proceedings.

front-page articles bearing the headlines "2 Popular Diet Pills Linked to Problems with Heart Valves" and "Diet Drug Patients Get Heart Warning." (*Id.* ¶ 6.)

News of the Mayo Clinic announcement was also featured on the front pages of regional papers across the country. (*Id.* ¶¶ 7-17.) The *Boston Herald*, for example, printed a front-page report on the Mayo Clinic announcement and the possibility that additional warning labels may be required on the drugs in light of the announcement. (*Id.* ¶ 11.) Similar stories appeared in the *Boston Globe* and other Massachusetts newspapers, as well as newspapers in Florida,¹⁵ Ohio, New England (*id.* ¶¶ 11, 13 & 17) and numerous other local and regional papers across the country. (*Id.* ¶¶ 7-17.) The story was also featured prominently in television news coverage. (*Id.* ¶¶ 10, 14.) There was more publicity following the announcement by the FDA of additional cases of valvulopathy in August 1997. (*Id.* ¶ 18.)

On September 15, 1997, Redux and Pondimin were withdrawn from the market by Wyeth and Indevus. Both companies and the FDA issued press releases announcing the withdrawal and advising persons using the drugs to see their physicians. (*Id.* ¶¶ 19, 22-23.) Wyeth also placed advertisements about the withdrawal in regional and local newspapers and sent letters to physicians. (*Id.* ¶¶ 20-21.) The withdrawal was a leading story on most national and regional news broadcasts and a front page article in newspapers around the country. (*Id.* ¶¶ 24-46.)

Tom Brokaw began the "NBC Nightly News" on September 15, 1997, with the following: "Good evening. Two of the most popular diet drugs in America are off the market tonight, recalled by their manufacturers after a wave of reports that they can bring on heart problems." (*Id.* ¶ 24.) Dan Rather led the "CBS Evening News" with a similar announcement. (*Id.*) The next day, the story was featured on all the national network morning shows. Ann Curry of the "Today" show introduced the story with the declaration: "A serious warning from the Food and

¹⁵ Plaintiff Palomba, who currently claims Connecticut residence, appears to have been in Florida when she used Redux. (Palomba Product Identification Due Diligence Statement, Armstrong Decl., Ex. 1.)

Drug Administration. If you are using two popular diet drugs, stop. The drugs are being recalled because they could cause heart problems." (*Id.* ¶ 25.) A Boston news broadcast observed that "health concerns about the diet drugs Fen-Phen and Redux have consumed news reports lately, and yesterday the drug makers announced that they are pulling them off the market." (*Id.* ¶ 37.)

The withdrawal and potential heart problems associated with the drugs was also covered extensively in the national and local print media. (*Id.* ¶¶ 24-46.) For example, the *Boston Herald*'s article entitled "FDA Warning Sparks Recall of Top Diet Pills" reported the withdrawal of the drugs, as well as Wyeth's attempt to contact patients about the withdrawal. (*Id.* ¶ 37.) As Judge Bartle of the MDL observed:

The withdrawal of Pondimin and its chemical cousin Redux from the market on September 15, 1997 was subject to an extraordinary amount of publicity by Wyeth, the federal government and national and local media. Immediately after removing the drugs from the market, Wyeth issued a press release advising patients who had used the diet drugs to consult their physicians. It included the same message in full page advertisements that it purchased in leading national and regional newspapers. These advertisements led with a banner in large print, stating "An Important Message to Patients Who Have Used Pondimin or Redux." Furthermore, Wyeth sent a "Dear Health Care Provider Letter" to approximately 450,000 doctors and pharmacists informing them of the withdrawal of the drugs from the market and of the potential association between use of the drugs and instances of valvular heart disease.

The federal government also acted swiftly to apprise former diet drug users about the dangers potentially linked to use of the diet drugs. The FDA issued a press release in September, 1997 announcing the withdrawal of the products and cautioning consumers that approximately 30 percent of diet drug patients who were evaluated had abnormal echocardiograms, albeit no symptoms. . . .

The efforts undertaken by Wyeth and the federal government to inform diet drug consumers about the possible dangers linked to fen-phen were enhanced significantly by national and local media, which extensively broadcast and published stories about fen-phen and its withdrawal from the market. Reports about the removal of the drugs became national headlines on nightly news programs and the networks' morning shows. All of these reports emphasized the possible connection between fen-phen and heart valve problems. The print media was no less generous in its treatment of the story.

Ferrell v. Wyeth (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.), MDL No. 1203, Civil Action No. 03-20094, slip op. at 12-13 (E.D. Pa. Sept. 5, 2003).

Likewise, another federal court has stated:

The media coverage prominently reported possible links to heart conditions caused by the drugs and covered the period from September 15, 1997 into November 1997, followed by stories regarding lawsuits in August 1999 in which a jury found

Wyeth's predecessor liable. In the face of the veritable blizzard of publicity concerning the withdraw[ing] of the drugs and the possible injuries which resulted, particularly in the fall of 1997, there is no reasonable possibility that a Texas court would find that it was impossible or exceedingly difficult for [the plaintiff] to have discovered her injury no earlier than two years prior to the date on which she filed her petition in state court[].

Speaker v. Wyeth-Ayerst Labs., No. 3-03-CV-1576-L, 2003 WL 22938955, at *4 (N.D. Tex. Dec. 3, 2003).¹⁶

D. This Lawsuit Was Not Timely Filed

For this lawsuit to have been timely filed on December 11, 2003, Plaintiffs' negligence, fraud, and "strict liability" claims must have accrued after December 10, 2000. Their 93A claims must have accrued after December 10, 1999. However, as noted above, Plaintiffs were on notice of their potential claims against Indevus and could have discovered their injuries, if any, on or about September 15, 1997. In addition, the association between diet drugs and valvular heart disease continued to be the subject of intense media scrutiny from September 15, 1997, through December 10, 1999, and through December 10, 2000.

For example, on November 14, 1997, the U.S. Department of Health and Human Services published health warnings for former users of Pondimin and Redux, including a recommendation that they see their physicians. (*Taylor Decl.* ¶ 47.) This recommendation led to another massive wave of national and local publicity on both television and in the print media. (*Id.* ¶¶ 47-62.) Other waves of publicity followed the first jury verdict against Wyeth in a Pondimin case in August 1999, and Wyeth's announcement of a national class action settlement in October 1999. (*Id.* ¶¶ 63-67.) The notice program required by the settlement began in November, 1999, and substantial notice efforts pursuant to the program were undertaken during the relevant limitations period in this action. (*Id.* ¶¶ 68-70.) As a matter of law, the massive publicity surrounding the

¹⁶ See also *Jamison v. Wyeth (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)*, MDL No. 1203, Civil Action Nos. 03-20317, et al., slip op. at 6 (E.D. Pa. Mar. 5, 2004) (holding that massive publicity triggered the statute of limitations); *French v. Wyeth (In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.)*, MDL No. 1203, Civil Action No. 03-20353, et al., slip op. at 7-9 (E.D. Pa. Feb. 18, 2004) (discussing the extensive publicity surrounding the withdrawal of Redux and Pondimin); *Moseley v. Wyeth*, No. Civ-02-1120-M, 2002 U.S. Dist. LEXIS 26759, at *8-9 (W.D. Okla. Sept. 13, 2002) ("[T]he widespread media coverage surrounding the Phen-Fen diet drugs from September 1997 through February 2000 is more than sufficient to impute knowledge to plaintiff about her claims against [her physician].").

withdrawal of Redux and Pondimin triggered the running of the statute of limitations. *See, e.g., Cummings Props. Mgmt., Inc. v. W.R. Grace & Co.-Conn.*, No. 912641, 1994 WL 879462, at *6-7 (Mass. Super. Ct. Jan. 19, 1994); *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387, 403 (5th Cir. 1998) (holding that plaintiff was on notice of claim as a result of numerous media reports regarding the health effects of Agent Orange, related litigation and a class action settlement).¹⁷

II. The Statute of Limitations Was Not Tolled by Fraudulent Concealment

Plaintiffs may argue that the statute of limitations should be tolled due to fraudulent concealment. For example, Plaintiffs allege that Indevus stated in its 2002 Annual Report that the incidence of cardiac valvulopathy attributed to diet drugs was less than suggested by FDA's initial data. (Compl. ¶ 94.) Plaintiffs also allege that Indevus has denied in litigation that it concealed the risks of Redux. (Compl. ¶ 95.) The contention that either of these statements would support a claim for fraudulent concealment is without merit. Initially, the statement from Indevus' 2002 Annual Report that Plaintiffs cite does not deny that an association between Pondimin and Redux and valvular heart disease has been observed in studies, including a study sponsored by Indevus. (Armstrong Decl., Ex. 9 at 22-23.)

Moreover, as noted above, Plaintiffs' claims accrued in 1997. In its 1997 Annual Report, Indevus reported that the FDA had observed abnormal echocardiogram findings in 92 of 291 Redux and Pondimin users¹⁸ and summarized the preliminary recommendations for the medical management of people who took Pondimin or Redux issued by the Department of Health and Human Services on November 13, 1997. (Armstrong Decl., Ex. 8 at 8-9.) Further, a company's denial of liability for a particular act is not fraudulent concealment. *See Estate of Sarocco v. Gen.*

¹⁷ See also *Hughes v. Vanderbilt Univ.*, 215 F.3d 543, 548 (6th Cir. 2000); *Hartnett v. Schering Corp.*, 2 F.3d 90, 93 (4th Cir. 1993); *United Klans of Am. v. McGovern*, 621 F.2d 152, 154-55 (5th Cir. 1980); *Ball v. Union Carbide Corp.*, 212 F.R.D. 380, 394 (E.D. Tenn. 2002); *Viele v. Ford Motor Co.*, No. 98-CV-1460, 1999 WL 123589, at *2 (N.D.N.Y. Feb. 23, 1999), aff'd, 201 F.3d 433 (2d Cir. 1999); *In re Ford Motor Co. Bronco II Prod. Liab. Litig.*, 982 F. Supp. 388, 393 (E.D. La. 1997).

¹⁸ It was this 30 percent incidence originally reported by the FDA that the 2002 Annual Report referred to as the "FDA's preliminary analysis."

Elec. Co., 939 F. Supp. 91, 97-98 (D. Mass. 1996) ("The defendants' general, repeated public denial of any link between PCB's and cancer does not constitute fraudulent concealment as a matter of law. A defendant is not obliged to acknowledge liability, or to adopt a plaintiff's theory of a case, in order to avoid a defense of this sort.").

Fraudulent concealment requires proof that the defendant concealed the existence of the plaintiff's cause of action through "some affirmative act done with intent to deceive." *Szymanski v. Boston Mut. Life Ins. Co.*, 56 Mass. App. Ct. 367, 380-81, 778 N.E.2d 16, 27 (2002) (citation omitted). As such, unless there is a fiduciary relationship, silence is not fraudulent concealment. *See Lynch v. Signal Fin. Co. of Quincy*, 367 Mass. 503, 508, 327 N.E.2d 732, 735 (1975). Nor will the statute be tolled – even in cases of actual fraud – if the plaintiff has "actual knowledge" of the facts giving rise to his cause of action, or the means to acquire the facts on which his cause of action is based. *Id.* at 507-08, 327 N.E.2d at 735.¹⁹

For example, in *Olsen*, the plaintiff argued that the defendants were estopped from relying on the statute of limitations because one defendant told him that his asthma was not permanent and the other told him that the substance at issue did not cause asthma. *See* 388 Mass. at 176, 445 N.E.2d at 612. The Supreme Judicial Court found such arguments to be without merit. *Id.* "Unless the defendants 'made representations they knew or should have known would induce the plaintiff to put off bringing suit and . . . the plaintiff did in fact delay in reliance on the representations,' there is no estoppel." *Id.* (quoting *White v. Peabody Constr. Co.*, 386 Mass. 121, 134-35, 434 N.E.2d 1015 (Mass. 1982)). Likewise in *Malapanis v. Shirazi*, 21 Mass. App. Ct. 378, 487 N.E.2d 533 (1986), the court held that a physician's statement that the patient's outcome was not unusual did not negate plaintiff's notice of his claim. *Id.* at 385-86, 487 N.E.2d at 538. "If someone, like the plaintiff in this case, is deemed to know the facts upon which his claim rests, there can be no fraudulent concealment." *Id.* at 386 n.8, 487 N.E.2d at 538 n.8. As noted

¹⁹ See also *Stark v. Advanced Magnetics, Inc.*, 50 Mass. App. Ct. 226, 234, 736 N.E.2d 434, 442-43 (2000); *Burbridge v. Bd. of Assessors*, 11 Mass. App. Ct. 546, 549-50, 417 N.E.2d 477, 480 (1981) ("[E]stoppel provision of G.L. c. 260, § 12 is not generally available if the plaintiff is capable of discovering the facts allegedly concealed.") (citing *Walker v. Soule*, 138 Mass. 570, 572 (Mass. 1885)).

above, Plaintiffs were on notice of facts sufficient to enable them to pursue their claims in the fall of 1997. Allegations of fraudulent concealment cannot, as a matter of law, save their claims from a limitations bar.

III. Class Action Tolling Does Not Save the Plaintiffs' Claims

In *American Pipe & Construction Co. v. Utah*, 414 U.S. 538 (1974) and *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345 (1983), the U.S. Supreme Court held that the commencement of a class action tolls the running of the statute of limitations for members of the class during the pendency of the class action. See *American Pipe*, 414 U.S. at 550-51; *Crown Cork*, 462 U.S. at 349-50, 353-54. *American Pipe* and *Crown Cork*, however, involved federal causes of action and federal class actions. The Massachusetts Supreme Judicial Court has never recognized class action tolling. See *Mass. Elec. Co. v. Mass. Comm'n Against Discrimination*, 375 Mass. 160, 165 n.2, 375 N.E.2d 1192, 1197 n.2 (1978) ("We need not decide at this time whether the statute of limitations is tolled for them by the initial filing of the class action."). In addition, for the reasons set forth below, class action tolling would not, in any event, preserve the Plaintiffs' claims in this case, where the drugs at issue were withdrawn from the market more than six and a half years ago.

A. Massachusetts Has Never Adopted Class Action Tolling and Would Not Recognize It on These Facts

Statutes of limitations are the product of the legislature. See *Hernandez v. City of Boston*, 394 Mass. 45, 48, 474 N.E.2d 166, 168 (1985). Massachusetts courts have been extremely reluctant to override legislative prerogative in this area. In Massachusetts, "[e]quitable tolling is used 'only sparingly,' and is generally limited to specified exceptions." *Schafnacker v. Raymond James & Assocs., Inc.*, 425 Mass. 724, 728, 683 N.E.2d 662, 665 (1997) (citation omitted). Massachusetts has never recognized equitable tolling based on the pendency of another action. Cf. *id.* at 727-30, 683 N.E.2d at 665-67 (holding that filing an arbitration claim did not toll the statute of limitations).²⁰

²⁰ In *DiCerbo v. Commissioner of Department of Employment & Training*, 54 Mass. App. Ct. 128, 763 N.E.2d 566 (2002), a Massachusetts appellate court observed, in *dicta*, that a motion to

Furthermore, Massachusetts would not adopt class action tolling in a case such as this, involving mass tort, personal injury claims. Courts have noted two separate reasons why the U.S. Supreme Court's reasoning in *American Pipe* should not apply in cases such as this. First, personal injury classes are rarely, if ever, certified. Second, the members of mass tort, personal injury classes are too disparate and amorphous to give a defendant sufficient notice, for limitations purposes, of the claimants and claims asserted against it. As the California Supreme Court explained:

[B]ecause personal-injury mass-tort class-action claims can rarely meet the community of interest requirement in that each member's right to recover depends on facts peculiar to each particular case, such claims may be presumptively incapable of apprising defendants of "the substantive claims being brought against them," a prerequisite, in our view, to the application of *American Pipe*. This being so, putative class members would be ill advised to rely on the mere filing of a class action complaint to toll their individual statute of limitations. The presumption, rather, should be to the contrary – i.e., that lack of commonality will defeat certification and preclude application of the *American Pipe* tolling doctrine.

Jolly v. Eli Lilly & Co., 751 P.2d 923, 937-38 (Cal. 1988) (citations omitted). Likewise, in *Bell v. Showa Denko K.K.*, 899 S.W.2d 749 (Tex. App. 1995), a Texas appellate court observed that Texas had adopted class action tolling only in a suit involving "a readily discernable group of people claiming injury to certain property rather than personal injury." *Id.* at 758. "That distinction," stated the court, "is important in determining whether the defendants have received fair notice of the existence of a claim by the filing of a class suit." *Id.*; see also *Vaught v. Showa Denko K.K.*, 107 F.3d 1137, 1147 (5th Cir. 1997) (holding that class action tolling did not apply to personal injury claims); *Barela v. Showa Denko K.K.*, No. CIV. 93-1469 LH/RLP, 1996 WL 316544, at *4 (D.N.M. Feb. 28, 1996) ("[M]ost federal courts . . . refuse to permit the use of the class-action device in mass-tort cases, . . . and tolling in such instances would be inappropriate.") (first ellipsis in original; citation omitted).

substitute a new class representative on remand would not be untimely because "as to putative class members who wish to intervene, the statute of limitations is tolled upon the filing of the complaint." *Id.* at 136 n.13, 763 N.E.2d at 572 n.13. This statement, which appears in a footnote, is in no way essential to the court's holding and, therefore, the court's opinion contains no analysis of this issue. The court did not consider the competing public policy considerations which underlie a statute of limitations and tolling or review relevant Massachusetts authority – or lack thereof – to support its comment.

Indeed, numerous courts have noted that mass tort, personal injury actions are inappropriate for class certification due to the overwhelming number of individual issues typically presented, especially with respect to the question of medical causation.²¹ The Massachusetts Supreme Judicial Court has also commented on the unsuitability of mass tort, personal injury actions for class certification. *See Fletcher v. Cape Cod Gas Co.*, 394 Mass. 595, 601, 603, 477 N.E.2d 116, 120, 122 (1985) (affirming denial of certification in formaldehyde litigation, noting that "questions relating to proximate cause of specific injuries," among other individual issues, weighed against certification); *see also id.* at 604 n.8, 477 N.E.2d at 122 n.8 (observing that the Federal Rule 23 Advisory Committee's caution against certification of mass torts supported its conclusion); *Weld v. Glaxo Wellcome Inc.*, 434 Mass. 81, 93, 746 N.E.2d 522, 532 (2001) (noting that the class action before it was not a mass tort involving a "large plaintiff class[] whose members have suffered severe personal injury or death"). Courts have also noted, when denying class certification, that personal injury claimants typically have a strong interest in controlling litigation involving their claims. *See, e.g., Kurczi v. Eli Lilly & Co.*, 160 F.R.D. 667, 680 (N.D. Ohio 1995). Thus, given that Massachusetts does not permit opt-outs,²² it seems even more unlikely that Massachusetts courts would certify such claims for class treatment. Indeed, Massachusetts courts have never certified a personal injury class action in any reported decision.²³

²¹ See, e.g., *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1081, 1084-85 (6th Cir. 1996); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 203, 205-06 (D. Minn. 2003); *In re Paxil Litig.*, 212 F.R.D. 539, 551 (C.D. Cal. 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61, 65 & nn.34-35, 66-67 (S.D.N.Y. 2002); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 208 F.R.D. 625, 630-31 (W.D. Wash. 2002).

²² See *Fletcher*, 394 Mass. at 602, 477 N.E.2d at 121.

²³ Indevus is not asking this Court to address itself to the merits of class certification in the diet drug litigation. Rather, the question before this Court is whether class certification of a mass tort, personal injury action is such a remote possibility, giving the overwhelming precedent against certification of such classes, that the rationale of *American Pipe* does not make sense in such cases. There would be no conservation of judicial resources, while the public policy underlying the statute of limitations would be severely undermined and defendants significantly prejudiced.

Further, the reasons that courts deny class certification in personal injury actions underscores the inequity that would result to a defendant from class action tolling. As one court explained:

[T]he issue whether [a drug] caused physical injury to a specific class member will depend on his or her unique characteristics such as family and medical background, preexisting medical conditions, age, gender, life style, drug or alcohol use, quantity of [drug] ingested, duration of course of treatment, whether it was used as an initial therapy and whether [the drug] was used alone or in conjunction with other drugs.

In re Rezulin Prods. Liab. Litig., 210 F.R.D. 61, 66-67 (S.D.N.Y. 2002). While a defendant faced with a personal injury class action might take steps to preserve its own evidence, it can do nothing to preserve vital evidence that is highly individualized and critical to the outcome of the case, such as evidence of product identification, product use or misuse, what information the plaintiff was given regarding the product by her physician or others, the plaintiff's medical history, causation and damages. As a result, if class members' claims are tolled, a "defendant will potentially have to face a barrage of stale claims. These are the exact types of claims that the . . . statute of limitations is designed to prevent." David Bober, *Cross-Jurisdictional Tolling: When and Whether a State Court Should Toll Its Statute of Limitations Based on the Filing of a Class Action in Another Jurisdiction*, 32 Seton Hall L. Rev. 617, 626-28 (2002) (footnote omitted). Accordingly, even were Massachusetts to adopt a rule of class action tolling, it would not do so in a case such as this.

B. Class Action Tolling Would Not Save the Plaintiffs' Claims

Assuming, *arguendo*, that Massachusetts did permit class action tolling, it would also recognize the limitations on the doctrine that have developed since *American Pipe* was first decided:

- (1) A class action filed in other jurisdictions will not toll the statute of limitations in a subsequent case filed in Massachusetts state court.
- (2) Only the first filed class action in the relevant jurisdiction will toll the statute of limitations.

- (3) At the end of the toll, plaintiffs must file their individual lawsuits within the time period provided by the state's savings statute.
- (4) The toll does not apply to claims not asserted in the class action.

Such restrictions on the tolling doctrine are essential to prevent indefinite suspension of statutes of limitations and the complete frustration of the policies they serve.²⁴

1. The Court Should Consider Only Massachusetts Class Actions

Most courts to have considered the question have rejected so-called cross-jurisdictional tolling. In other words, an action filed in another jurisdiction should have no effect on the statute of limitations in an action filed in Massachusetts. See *Wade v. Danek Med., Inc.*, 182 F.3d 281, 287-88 (4th Cir. 1999) (applying Virginia law); *Thelen v. Mass. Mut. Life Ins. Co.*, 111 F. Supp. 2d 688, 694-95 (D. Md. 2000) (applying Maryland law); *Barela*, 1996 WL 316544, at *4 (applying New Mexico law); *Portwood v. Ford Motor Co.*, 701 N.E.2d 1102, 1104-05 (Ill. 1998); *Ravitch v. Pricewaterhouse*, 793 A.2d 939, 943-45 (Pa. Super. Ct. 2002), *appeal denied* mem., 818 A.2d 505 (Pa. 2003); *Johnson v. Am. Home Prods. Corp.*, No. 0371MARCH TERM, 2002, 2003 WL 21467099, at *4 (Pa. Ct. Com. Pl. June 11, 2003) (diet drug litigation); *Maestas v. Sofamor Danek Group, Inc.*, 33 S.W.3d 805, 808-09 (Tenn. 2000); *Bell*, 899 S.W.2d at 758 (Texas).

As the Illinois Supreme Court explained, the policy underlying the *American Pipe* doctrine (preventing protective filings by class members) applies only "when both actions are brought in the same court system." *Portwood*, 701 N.E.2d at 1104. Initially, Massachusetts has no significant interest in promoting the efficiency of the federal court system or the court systems of other states. See *Wade*, 182 F.3d at 287; *Maestas*, 33 S.W.3d at 808. At the same time, recognition of cross-jurisdictional tolling could "actually increase the burden on [a] state's

²⁴ In considering each of these limitations on *American Pipe* tolling, it should be remembered that Massachusetts courts have generally been very conservative with respect to doctrines (such as equitable tolling and the discovery rule) that would extend the time for a plaintiff to file suit. See (*Schafnacker*, 425 Mass. at 728, 683 N.E.2d at 665; *Krasnow*, 29 Mass. App. Ct. at 569-70, 562 N.E.2d at 1380.

court system, because plaintiffs from across the country may elect to file a subsequent suit in that state solely to take advantage of the generous tolling rule." *Portwood*, 701 N.E.2d at 1104; *see also Wade*, 182 F.3d at 287 (observing that "Virginia would be faced with a flood of subsequent filings once a class action in another forum is dismissed"); *Maestas*, 33 S.W.3d at 808 (noting that "Tennessee courts would become a clearinghouse for cases that are barred in the jurisdictions in which they otherwise would have been brought"). The prospect of a flood of cases is much more than theoretical for this Court. Prior to the instant action, the last activity in this Court involving the diet drug litigation was in October, 2001. Now, this Court is faced with lawsuits involving potentially 4,600 plaintiffs, most of whom very likely reside in states other than Massachusetts.²⁵

In addition, as Massachusetts courts have no control over the disposition of class actions in other courts, they "should not be required to entertain stale claims simply because the controlling statute of limitations expired while a [foreign] court considered whether to certify a class action." *Portwood*, 701 N.E.2d at 1104; *accord Wade*, 182 F.3d at 288. Allowing courts in other jurisdictions to control the commencement of Massachusetts' statute of limitations would interfere with the Massachusetts legislature's "power to adopt statutes of limitations and the exceptions to those statutes." *Maestas*, 33 S.W.3d at 809.

Only two putative class actions involving Redux and Indevus have been filed in Massachusetts. The first, *Bilodeaux v. Interneuron Pharmaceuticals Inc., et al.*, No. 97-5160-B, was filed in the Superior Court for Suffolk County on September 26, 1997. (*Bilodeaux* Compl., Armstrong Decl., Ex. 10.) The plaintiff sought certification of "a class consisting of all persons in the United States who purchased and/or used fenfluramine (Pondimin) and/or dexfenfluramine (Redux) designed, manufactured, marketed, sold and/or placed in the stream or interstate

²⁵ In February and March of 2004, Indevus received demand letters pursuant to G.L. c. 93A for 2,634 claimants from Sugarman, Rogers, the attorneys for Plaintiffs here. It received 93A demand letters for 715 more claimants from another Boston law firm, Brinkley, Sears & Sorett, P.A. It received 93A demand letters for 1,248 additional claimants from out-of-state law firms. The total number of claimants is 4,597.

commerce by the defendants." (*Bilodeaux* Compl. ¶25.) *Bilodeaux* was dismissed, by stipulation, 101 days later, on January 5, 1998. (*Bilodeaux* Stipulation of Dismissal, Armstrong Decl., Ex. 11.)

The other putative class action, *Doherty, et al. v. Interneuron Pharmaceuticals Inc., et al.*, No. 98-928, was filed in the Superior Court for Middlesex County on February 25, 1998. (*Doherty* Compl., Armstrong Decl., Ex. 12.) According to the original complaint, the plaintiffs sought to represent a class "consisting of all Massachusetts residents who were prescribed and consumed, and/or purchased, fenfluramine (Pondimin) and/or dexfenfluramine (Redux) designed, manufactured, marketed, sold, co-promoted, supplied and/or placed in the stream of interstate commerce by one or more of the defendants." (*Doherty* Compl. ¶45.) On April 27, 2000, the *Doherty* plaintiffs moved for certification of the following class with respect to their claims against Indevus:

All residents of the United States who have ingested dexfenfluramine (Redux), either singularly or in combination with phentermine hydrochloride (phentermine). The class shall not include (a) any person who has been diagnosed with any heart valve regurgitation, primary pulmonary hypertension, or any injury caused by the ingestion of any or all of these medications; (b) any person who is asymptomatic and whose claim arose under the law of a state which does not recognize claims for medical monitoring absent injury; and (c) residents of West Virginia and Pennsylvania, states having a court which has certified an action for medical monitoring against defendant Interneuron Pharmaceuticals, Inc.

(*Doherty* Mot. for Class Certification at 1, Armstrong Decl., Ex. 13.) Pursuant to stipulation of the parties, *Doherty* was dismissed on July 11, 2002. (*Doherty* Judgment, Armstrong Decl., Ex. 14.) For the reasons discussed below, even assuming a toll based upon *Bilodeaux* and/or *Doherty*, Plaintiffs' claims would still be barred.

2. Tolling Should Be Limited to the First Filed Class Action

As numerous courts have held, only the first class action filed operates to toll the statute of limitations. See, e.g., *Basch v. Ground Round, Inc.*, 139 F.3d 6, 11-12 (1st Cir. 1998); *Salazar-Calderon v. Presidio Valley Farmers Ass'n*, 765 F.2d 1334, 1351 (5th Cir. 1985); *Piney Woods Country Life School v. Shell Oil Co.*, 170 F. Supp. 2d 675, 685 (S.D. Miss. 1999); *Abrams v. Communications Workers of Am.*, No. 87-2816, 1992 WL 88038, at *3-4 (D.D.C.

Apr. 14, 1992); *Smith v. Cutter Biological*, 770 So. 2d 392, 410 (La. Ct. App. 2000); *Bartlett v. Miller & Schroeder Mun., Inc.*, 355 N.W.2d 435, 440-41 (Minn. Ct. App. 1984). The purpose of this corollary to *American Pipe* is to prevent plaintiffs from tolling the period of limitations indefinitely by filing successive class actions. See *Basch*, 139 F.3d at 11-12; *Salazar-Calderon*, 765 F.2d at 1351; cf. *Griffin v. Singletary*, 17 F.3d 356, 359 (11th Cir. 1994) ("Plaintiffs may not piggyback one class action onto another and thus toll the statute of limitations indefinitely.") (citation omitted).

Here, the first filed class action was *Bilodeaux*, which was dismissed on January 5, 1998, almost six years before the instant action was filed. Clearly, *Bilodeaux* does not save the Plaintiffs' claims.

3. Plaintiffs Were Required To File Their Individual Actions Within The Applicable Period Provided by Massachusetts' Savings Statute

The issue of class action tolling raises two initial questions. The first is whether the running of the statute of limitations is tolled by the pendency of a class action. For the reasons discussed above, Massachusetts courts would answer this first question "No." However, even assuming that there was a toll, a court must determine the applicable "tolling effect." In this case, in order to take advantage of any class action toll, Plaintiffs were required to file their lawsuit within one year after the toll ended. As a result, even if one takes into account the *Doherty* lawsuit, Plaintiffs' claims would still be barred.

Initially, *Doherty* has no relevance to the claims of the three out-of-state plaintiffs in this action. It is axiomatic that a plaintiff must be a member of the class upon which he relies to assert a toll. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 219-20 (E.D.N.Y. 2003); *Shimazaki Communications, Inc. v. Am. Tel. & Tel. Co.*, 647 F. Supp. 10, 14 (S.D.N.Y. 1986) (noting that class certification proceedings made clear that the contemplated class did not include plaintiff and that "it would have been totally unreasonable for [plaintiff] to have viewed itself as a member of that class"). In this case, Plaintiffs Paul, Rose and Palomba were never members of the *Doherty* class. When the action was first filed, it excluded

non-Massachusetts residents. When the *Doherty* plaintiffs attempted to expand the class definition nationwide, they specifically excluded personal injury claimants. *See Johnson*, 2003 WL 21467099, at *5 (holding that personal injury claimants in diet drug litigation could not rely on a medical monitoring class action to toll their statutes of limitations); *Singer v. Eli Lilly & Co.*, 549 N.Y.S.2d 654, 660 (App. Div. 1990) (holding that medical monitoring class action did not toll personal injury claimants' statute of limitations); *see also Jolly*, 751 P.2d at 936-37 (holding that medical monitoring class did not provide defendants with sufficient notice to toll statute of limitations with respect to personal injury claims). Accordingly, the claims of Plaintiffs Paul, Rose and Palomba must be dismissed with prejudice.

Even though plaintiff Sawyer alleges Massachusetts residence, her claim is likewise barred for failure to file within one year after the class definition in *Doherty* was revised. As the U.S. Supreme Court explained in *Chardon v. Fumero Soto*, 462 U.S. 650 (1983), there are three possible tolling effects: (1) suspension of the statute during the time the toll is in effect ("suspension"), (2) the statute begins to run anew when the toll ends ("renewal"), and (3) a new specified period (e.g., six months or a year) is provided during which the plaintiff must re-file ("extension"). *See id.* at 652 n.1. The Supreme Court further held that in cases where state law supplies the statute of limitations, the tolling effect is that provided for in the most closely analogous state savings statute. As the Court explained:

After class certification is denied, [the] federal interest is vindicated as long as each unnamed plaintiff is given as much time to intervene or file a separate action as he would have under a state savings statute applicable to a party whose action has been dismissed for reasons unrelated to the merits, or, in the absence of a statute, the time provided under the most closely analogous state tolling statute.

Id. at 661.

The rule announced in *Chardon* is supported by strong public policy and profound common sense. The purpose of *American Pipe* tolling is to prevent multiple lawsuits from being filed during the pendency of a class action. That objective evaporates as soon as the toll ends

due to dismissal, denial of class certification or revision of the class definition.²⁶ See *id.* at 661. At that point, courts must once again be mindful of the policies underlying statutes of limitation. Both the Massachusetts Supreme Judicial Court and the U.S. Supreme Court have noted that statutes of limitations serve the important public purpose of promoting social stability. See *Olsen*, 388 Mass. at 175, 445 N.E.2d at 612; *Wood v. Carpenter*, 101 U.S. 135, 139 (1879) (cited with approval in *Olsen*, 388 Mass. at 175, 445 N.E.2d at 612). In addition, statutes of limitations represent a legislatively struck balance between the rights of plaintiffs and defendants. As the U.S. Supreme Court has explained:

Statutes of limitations, which "are found and approved in all systems of enlightened jurisprudence," represent a pervasive legislative judgment that it is unjust to fail to put the adversary on notice to defend within a specified period of time and that "the right to be free of stale claims in time comes to prevail over the right to prosecute them." . . . [A]lthough affording plaintiffs what the legislature deems a reasonable time to present their claims, they protect defendants and the courts from having to deal with cases in which the search for truth may be seriously impaired by the loss of evidence, whether by death or disappearance of witnesses, fading memories, disappearance of documents, or otherwise.

United States v. Kubrick, 444 U.S. 111, 117 (1979) (citations omitted). Accordingly, with respect to the discovery rule, one Massachusetts appellate court observed:

Determining how far to extend the discovery rule requires a balancing between competing policies: the policy of fairness to claimants who may have incomplete knowledge of the facts giving rise to their claim . . . and the policies of repose and fairness to defendants, who may be disadvantaged by delay in defending themselves . . . That balance seems to have been struck in Massachusetts in favor of a somewhat more limited discovery rule than exists in many other jurisdictions.

Krasnow, 29 Mass. App. Ct. at 569-70, 562 N.E.2d at 1380.

A savings statute represents the legislature's considered judgment as to where to strike this balance. It protects plaintiffs whose claims may be dismissed for reasons other than on the

²⁶ It is clear that revision of a class definition to exclude either the plaintiff or the defendant ends the toll. See *In re Indep. Serv. Org. Antitrust Litig.*, No. MDL-1201, 1997 WL 161940, at *3 (D. Kan. Mar. 12, 1997) (noting that tolling ends when the class definition is narrowed to exclude the individual); *Kidder v. Elec. Data Sys.*, No. 178021, 1996 WL 33357054, at *1 (Mich. Ct. App. Oct. 8, 1996) (holding that tolling ended when the class was redefined "in a manner that excluded plaintiff as a potential member of the class"); *Lindner Dividend Fund, Inc. v. Ernst & Young*, 880 F. Supp. 49, 54 (D. Mass. 1995) (holding that class action tolling did not extend to defendant who was not named in an amended and consolidated class action complaint).

merits by permitting them to re-file their actions within a reasonable time; it protects defendants from stale claims; and it promotes the overriding social concern for stability and repose. On the other hand, there is simply no reason to allow plaintiffs, whose claims accrued many years ago, another two or three years in which to file suit after a class action toll has ended. As the U.S. Eleventh Circuit Court of Appeals has noted, *American Pipe* should not be applied in a fashion that "would leave cases in limbo for years at a time." *Armstrong v. Martin Marietta Corp.*, 138 F.3d 1374, 1388 (11th Cir. 1998). "The potential length of the delay . . . increases the possibility that evidence will be lost, memories will fade, and witnesses will disappear." *Id.*; see also *Wood v. Combustion Eng'g, Inc.*, 643 F.2d 339, 347 (5th Cir. 1981) (noting that equitable principles could not excuse plaintiffs' failure to file their action for 19 months after they opted out of a class action).

As the U.S. Supreme Court observed in *Chardon*, reference to a state's most analogous savings statute to provide the tolling effect satisfies the *American Pipe* goal of preventing multiple filings while honoring the legitimate policy concerns that support state statutes of limitations. Accordingly, other courts have also held that a plaintiff invoking class action tolling must file within the period provided in the state's savings statute in order to save her claims from a limitations bar. See *Barela*, 1996 WL 316544, at *5 (holding that plaintiff had to file within six-month refiling period provided for in New Mexico's savings statute); *Waltrip v. Sidwell Corp.*, 678 P.2d 128, 133 (Kan. 1984) (holding that denial of certification "was tantamount to a dismissal otherwise than on the merits," so that plaintiffs had six months to file their action); *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 163 (Ohio 2002) (holding that plaintiff had one year, as provided in the state's saving statute, to file her claim after denial of class certification).

In this case, Massachusetts' savings statute requires a plaintiff whose action has been dismissed for "any matter of form" to refile within one year. See M.G.L.A. c. 260, § 32. Even ignoring the "first-filed" rule and considering *Doherty* as the relevant class action, Plaintiffs should have filed by April 27, 2001, one year after the date the *Doherty* class definition was

revised to exclude personal injury claimants. Indeed, this action was filed several months after the one year anniversary of *Doherty*'s dismissal on July 11, 2000.

4. Tolling Does Not Extend to the 93A Claims Not Pleaded in the Class Actions

When the Supreme Court adopted a class action tolling rule, it cautioned against abuse of the rule. Justice Blackmun observed that the court's decision in *American Pipe* "must not be regarded as encouragement to lawyers . . . to frame their pleadings as a class action . . . to attract and save members of the purported class who have slept on their rights." *American Pipe*, 414 U.S. at 561 (Blackmun, J., concurring). This view was reiterated by Justice Powell (joined by Justices Rehnquist and O'Connor) ten years later in *Crown, Cork*. See *Crown, Cork*, 462 U.S. at 353-54 (Powell, J., concurring). Justice Powell further noted:

The tolling rule of *American Pipe* is a generous one, inviting abuse. . . . It is important to make certain . . . that *American Pipe* is not abused by the assertion of claims that differ from those raised in the original class suit. [A] district court should . . . "preserve a defendant whole against prejudice arising from claims for which he has received no prior notice." Similarly, when a plaintiff invokes *American Pipe* in support of a separate lawsuit, the district court should take care to ensure that the suit raises claims that "concern the same evidence, memories, and witnesses as the subject matter of the original class suit," so that "the defendant will not be prejudiced." Claims as to which the defendant was not fairly placed on notice by the class suit are not protected under *American Pipe* and are barred by the statute of limitations.

Id. at 354-55 (citations omitted). Accordingly, in *Johnson v. Railway Express Agency, Inc.*, 421 U.S. 454 (1975), the Supreme Court noted that "the tolling effect given to the timely prior filings in *American Pipe* . . . depended heavily on the fact that those filings involved exactly the same cause of action subsequently asserted." *Id.* at 467; see also *Stutz v. Minn. Mining Mfg. Co.*, 947 F. Supp. 399, 404 n.2 (S.D. Ind. 1996) ("For the legal fiction of tolling to be equitable to the defendant, the claims in both the class action and the individual action must be identical."). As a result, the tolling rule should not extend to causes of action that were not pleaded in the class action complaint. See e.g., *Spann v. Cnty. Bank of N. Va.*, No. 03 C 7022, 2004 WL 691785, at *5-6 (N.D. Ill. Mar. 30, 2004); *Southwire Co. v. J.P. Morgan Chase & Co.*, No. 02-C-707-C, 2004 WL 414799, at *17-18 (W.D. Wis. Mar. 3, 2004); *Stutz*, 947 F. Supp. at 404 n.2; *Lindner*

Dividend Fund, Inc. v. Ernst & Young, 880 F. Supp. 49, 54-55 (D. Mass. 1995); *Burns v. Ersek*, 591 F. Supp. 837, 842-43 (D. Minn. 1984); *Jolly*, 751 P.2d at 936-37.

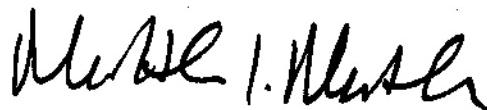
The *Bilodeaux* complaint did not contain a count for violation of G.L. c. 93A. (*Bilodeaux* Compl., Armstrong Decl., Ex. 10.) In *Doherty*, the plaintiffs did not assert a claim under G.L. c. 93A until they moved to amend on December 16, 1999. (*Doherty* Motion to Amend, Armstrong Decl., Ex. 15.) That motion, however, was never granted. (*Doherty* Docket, Armstrong Decl., Ex. 16.) Neither *Doherty* nor *Bilodeaux*, therefore, tolled the limitations period for Plaintiffs' 93A claims. Even if Plaintiffs were given credit based upon the motion to amend in *Doherty*, the tolling period, if any, would extend only from December 16, 1999, until April 27, 2000, when the class definition was revised. This four-month period would still be insufficient to save Plaintiffs' 93A claims.

CONCLUSION

For all the foregoing reasons, Plaintiffs' claims should be dismissed with prejudice.

Dated: April 23, 2004.
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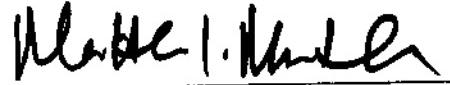
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CERTIFICATE OF SERVICE

I, Matthew J. Matule, hereby certify that on April 23, 2004, I caused a true copy of the foregoing Memorandum of Law in Support of Motion for Summary Judgment to be served by hand upon Edward J. Barshak, Esq., Sugarman, Rogers, Barshak & Cohen, P.C., 101 Merrimac Street, 9th Floor, Boston, MA 02114, and by first-class mail, postage prepaid, upon Samuel W. Lanham, Jr., Esq., Cuddy & Lanham, P.A., 470 Evergreen Woods, Bangor, ME 04401, and Neil D. Overholtz, Esq., Aylstock, Witkin & Sasser, P.L.C., 55 Baybridge Drive, P.O. Box 1147, Gulf Breeze, FL 32562-1147.

Dated: April 23, 2004


Matthew J. Matule